Remarks

Claims 1, 3-17, 28, 32, 34 and 36 are pending in this application. Claims 1, 3-15, 17, 28, 32, 34 and 36 are free of the prior art of record and are allowed. Claim 16 is amended herein.

Please amend claim 16 as indicated above in the Listing of the Claims. No new matter is introduced by way of amendment to claim 16, which is submitted to more clearly define the subject matter of the claim. Support for isolated cells is found, for example, in Example 2, beginning on page 39, line 6.

Consideration of Information Disclosure Statements

Applicant thanks the Examiner for his consideration of the Information Disclosure Statement (IDS) filed August 15, 2005. Receipt of the signed copy of the Form 1449 is acknowledged.

However, Applicant notes (as previously indicated in the Response and Request for Continued Examination filed February 17, 2005) that there is no indication that information disclosure statements filed July 27, 2001, and February 15, 2002, have been considered. Applicant respectfully requests that the Examiner return an initialed copy of the forms 1449 submitted on July 27, 2001, and February 15, 2002, indicating that the references cited therein have been considered. Copies of these PTO-1449 forms are included herewith for the Examiner's convenience.

Claim 16 is directed to statutory subject matter.

Claim 16 was rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Claim 16 is amended herein in accordance with the Examiner's suggestions, obviating this rejection. Claim 16 as amended is directed to an *isolated* cell. Applicant does not intend to claim any naturally occurring cell of a human subject to whom a claimed nucleic acid has been administered as a component of a vaccine. Applicant respectfully requests withdrawal of this rejection in light of the above amendments and remarks.

GW/TMH:gth 02/03/06 480776 I-001-01/0
PATENT

Attorney Reference Number 6395-64908-01
Application Number 09/826,115

Conclusion

Applicant believes that all pending claims are now in condition for allowance. A Notice of Allowance at an early date is respectfully requested. If any substantive issues remain, the Examiner is requested to telephone the undersigned prior to the preparation of any further written Action to arrange for a telephonic interview.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

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By 
Gwynedd Warren, Ph.D.
Registration No. 45,200

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ATTORNEY DOCKET NO. 14114.0332U3
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Chang

Confirmation No. 4134

Serial No. 09/826,115

Filed: April 4, 2001

For: "NUCLEIC ACID VACCINES FOR PREVENTION OF WEST NILE VIRUS INFECTION AND NONINFECTIOUS ANTIGEN FOR DIAGNOSTIC TEST"

Group Art Unit: 1642

Examiner: Unassigned

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT SUBMITTED IN ACCORDANCE WITH THE PROVISIONS OF 37 C.F.R. §1.97(b)

Commissioner for Patents
Washington, D.C. 20231

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811

February 15, 2002

Sir:

Submitted herewith on Form PTO 1449 is a listing of documents known to applicants and/or their attorneys pursuant to the requirements of 37 C.F.R. §1.56. A copy of each of these documents is enclosed.

Consideration of the cited documents and making the same of record in the prosecution of the above-noted application are respectfully requested.

ATTORNEY DOCKET NO. 14114.0332U3
SERIAL NO. 09/826,115

COPY

As these documents are considered to be timely filed, no fee is believed due. However, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

Mary Miller
Registration No. 39,303

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811
404/688-0770

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date listed below

Mary Miller — February 15, 2002
Mary Miller — Date

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Form PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rev. 7-80) PATENT AND TRADEMARK OFFICE LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)	ATTORNEY DOCKET NO.: 14114.0332U3	SERIAL NO. 09/826,115
	APPLICANT: Chang	
	FILING DATE: April 4, 2001	GROUP: Unassigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	B1	6,165,477	12/26/00	Ivy *et al.*			

FOREIGN PATENT DOCUMENTS

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	B2	Alvarez *et al.* A Phase I Study of Recombinant Adenovirus Vector-Mediated Delivery of an Anti-erbB-2 Single-Chain (sFv) Antibody Gene for Previously Treated Ovarian and Extraovarian Cancer Patients. *Hum. Gene Ther. 8:229-242 (January 20, 1997)*
	B3	Selay. The Choice of Carrier. *Synthetic Vaccines Volume I* (edited by Arnon) CRC Press Inc., Boca Raton, FL. pp. 83-92 (1987)
	B4	Clarke *et al.* Techniques For Hemagglutination And Hemagglutination-Inhibition With Arthropod-Borne Viruses. *Amer. J. Trop. Med. and Hyg.* 7:561-573 (1958)
	B5	Gruenberg *et al.* Partial Nucleotide Sequence and Deduced Amino Acid Sequence of the Structural Proteins of Dengue Virus Type 2, New Guinea C and PUO-218 Strains. *J. Gen. Virol.* 69:1391-1398 (1988)
	B6	Heinz *et al.* Flaviviruses. *Immunochemistry of Viruses II: The Basis for Serodiagnosis and Vaccines* (edited by von Regenmortel and Neurath) Elsevier Science Publishers Chapter 14, pp. 289-305 (1990)
	B7	Henchal *et al.* Dengue Virus-Specific And Flavivirus Group Determinants Identified With Monoclonal Antibodies By Indirect Immunofluorescence. *Amer. J. Trop. Med. Hyg.* 31:830-836 (1982)
	B8	Hubálek *et al.* West Nile Fever-a Reemerging Mosquito-Borne Viral Disease in Europe. *Emerg. Infect. Dis.* 5(5):643-650 (1999)
	B9	Kohler *et al.* Continuous cultures of fused cells secreting antibody of predefined specificity. *Nature* 256:495-497 (August 7, 1975)
	B10	Konishi *et al.* Avipox virus-vectored Japanese encephalitis virus vaccines: use as vaccine candidates in combination with purified subunit immunogens. *Vaccine* 12(7):633-638 (1994)
	B11	Kozak. Circumstances and Mechanisms of Inhibition of Translation by Secondary Structure in Eucaryotic mRNAs. *Mol. Cell. Biol.* 9(11):5134-5142 (November 1989)
	B12	Laemmli. Cleavage of Structural Proteins during the Assembly of the Head of Bacteriophage T4. *Nature* 277:680-685 (August 15, 1970)

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	B13	Lai *et al.* Immunization of Monkeys with Baculovirus Recombinant-expressed Dengue Envelope and NS1 Glycoproteins Induces Partial Resistance to Challonge with Homotypic Dengue Virus. In *Vaccines 90: Modern Approaches to New Vaccines including Prevention of AIDS*, Cold Spring Harbor Laboratory. Cold Springs Harbor, NY pp. 119-124 (1990)
	B14	Mason *et al.* Sequence of the Dengue-1 Virus genome in the Region Encoding the Three Structural Proteins and the Major Nonstructural Protein NS1. *Virology* 161:262-267 (1987)
	B15	Smithburn *et al.* A Neurotropic Virus Isolated From The Blood Of A Native Of Uganda. *Am. J. Trop. Med. Hyg.* 20:471-492 (1940)
	B16	Tardei *et al.* Evaluation of Immunoglobulin M (IgM) and IgG Enzyme Immunoassays in Serologic Diagnosis of West Nile Virus Infection. *J. Clin. Microbiol.* 38(6):2232-2239 (June 2000)
	B17	Tsai *et al.* Japanese Encephalitis Vaccines. In *Vaccines*, (3rd edition) (edited by Plotkin and Orenstein), W.B. Saunders Company, Philadelphia, PA. Chapter 27, pp. 672-710 (1999)
	B18	Tsai et al. Japanese Encephalitis Vaccines. In *Vaccines*, (2nd edition) (edited by Plotkin and Mortimer), W.B. Saunders Co., Philadelphia, PA. Chapter 24, pp. 671-713 (1994)
	B19	Yang *et al.* A p300/CBP-associated factor that competes with the adenoviral oncoprotein E1A. *Nature* 382:319-324 (July 25, 1996)

EXAMINER:	DATE CONSIDERED:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ATTORNEY DOCKET NO. 14114.0332U3
PATENT

COPY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	
Chang	:	
Serial No.: 09/826,115	:	Group Art Unit: Unassigned
Filed: April 4, 2001	:	Examiner: Unassigned
For: NUCLEIC ACID VACCINES FOR PREVENTION OF FLAVIVIRUS INFECTION	:	

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811

July 27, 2001

Sir:

Submitted herewith on form PTO 1449 is a listing of documents known to applicants and/or their attorneys in compliance with the requirements of 37 C.F.R. § 1.56. A copy of each of these documents is enclosed.

Consideration of the cited documents and making the same of record in the prosecution of the above-noted application are respectfully requested.

Applicants believe that this Information Disclosure Statement is being filed in accordance with 37 C.F.R. § 1.97(b)(3), i.e., before the mailing date of the first Office Action on the merits pertaining to the above-referenced application. Therefore, no fee is believed to be due. However, if a fee is

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required, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

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404/688-0770

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date shown below.

Mary L. Miller — July 27, 2001
Mary L. Miller — Date

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Form PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rev. 7-80) PATENT AND TRADEMARK OFFICE	ATTORNEY DOCKET NO.: 14114.0332U3	SERIAL NO. 09/826,115
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)	APPLICANT: Chang	
	FILING DATE: April 4, 2001	GROUP: Unassigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,514,375	05/07/96	Paoletti et al.	424	199.1	
	AB	5,494,671	02/27/96	Lai et al.	424	218.1	
	AC	5,229,293	07/20/93	Matsuura et al.	435	320.1	
	AD	5,021,347	06/04/91	Yasui et al.	435	235	
	AE	4,810,492	03/07/89	Fujita et al.	424	88	

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	AG	WO 93/06214	04/01/93	PCT			
	AH	WO 92/03545	03/05/92	PCT			
	AI	WO 90/01946	03/08/90	PCT			

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	AJ	Abstract, Japanese Patent Publication No. JP 05276941 "Non-infective structure particle preparation, useful as vaccine - by infecting preliminary flavivirus infected cell with cDNA integrated recombinant vaccinia virus, and then separating non-infective structure particles containing E protein of flavivirus," (October 26, 1993)
	AK	Deubel et al., Nucleotide Sequence and Deduced Amino Acid Sequence of the Nonstructural Proteins of Dengue Type 2 Virus, Jamaica Genotype: Comparative Analysis of the Full-Length Genome. *Virol.* 165: 234-244 (1988)
	AL	Davis et al., West Nile Virus Recombinant DNA Vaccine Protects Mouse and Horse from Virus Challenge and Expresses in Vitro a Noninfectious Recombinant Antigen That Can Be Used in Enzyme-linked Immunosorbent Assays. *J. Virol.* 75(9): 4040-4047 (2001) (published on-line April 4, 2001)
	AM	Konishi et al., Generation and Characterization of a Mammalian Cell Line Continuously Expressing Japanese Encephalitis Virus Subviral Particles. *J. Virol.* 75(5): 2204-2212 (2001)
	AN	Asnis et al., The West Nile Virus Outbreak of 1999 in New York: The Flushing Hospital Experience. *Clin. Infect. Dis.* 30: 413-418 (2000)
	AO	Chang et al., A Single Intramuscular Injection of Recombinant Plasmid DNA Induces Protective Immunity and Prevents Japanese Encephalitis in Mice. *J. Virol.* 74(9):4244-4252 (2000)
	AP	Garmendia et al., Recovery and Identification of West Nile Virus from a Hawk in Winter. *J. Clin. Microbiol.* 38(8): 3110-3111 (2000)

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	AQ	Johnson et al., Detection of Anti-Arboviral Immunoglobulin G by Using a Monoclonal Antibody-Based Capture Enzyme-Linked Immunosorbent Assay. *J. Clin. Microbiol.* 38(5): 1827-1831 (2000)
	AR	Martin et al., Standardization of Immunoglobulin M Capture Enzyme-Linked Immunosorbent Assays for Routine Diagnosis of Arboviral Infections. *J. Clin. Microbiol.* 38(5): 1823-1826 (2000)
	AS	Update: Surveillance for West Nile Virus in Overwintering Mosquitos --- New York, 2000. *Morb. Mortal. Wkly. Rep.* 49(09): 178-179 (Mar. 10, 2000)
	AT	Update: West Nile Virus Activity --- Northeastern United States, 2000. *Morb. Mortal. Wkly. Rep.* 49(36): 820-822 (Sept. 15, 2000)
	AU	Aberle et al., A DNA Immunization Model Study with Constructs Expressing the Tick-Borne Encephalitis Virus Envelope Protein E in Different Physical Forms. *J. Immunol.* 163: 6756-6761 (1999)
	AV	Anderson et al., Isolation of West Nile Virus from Mosquitoes, Crows, and a Cooper's Hawk in Connecticut. *Science* 286: 2331-2333 (Dec. 17, 1999)
	AW	Azevedo et al., Main features of DNA-based immunization vectors. *Braz. J. Med. Biol. Res.* 32(2): 147-153 (1999)
	AX	Jia et al., Genetic analysis of West Nile New York 1999 encephalitis virus. *Lancet* 354: 1971-1972 (Dec. 4, 1999)
	AY	Lanciotti et al., Origin of the West Nile Virus Responsible for an Outbreak of Encephalitis in the Northeastern United States. *Science* 286: 2333-2337 (Dec. 17, 1999)
	AZ	Mir et al., High-efficiency gene transfer into skeletal muscle mediated by electric pulses. *Proc. Nat. Acad. Sci. USA* 96: 4262-4267 (1999)
	BA	Ho et al. DNA vaccination induces a long-term antibody response and protective immunity against pseudorabies virus in mice. *Arch. Virol.* 143: 115-125 (1998)
	BB	Konishi et al., Induction of Protective Immunity against Japanese Encephalitis in Mice by Immunization with a Plasmid Encoding Japanese Encephalitis Virus Premembrane and Envelope Genes. *J. Virol.* 72(6):4925-4930 (June 1998)
	BC	Kuno et al., Phylogeny of the Genus *Flavivirus*. *J. Virol.* 72(1): 73-83 (Jan. 1998)
	BD	Lin et al., DNA Immunization with Japanese Encephalitis Virus Nonstructural Protein NS1 Elicits Protective Immunity in Mice. *J. Virol.* 72(1): 191-200 (Jan 1998)
	BE	Klinman et al., CpG motifs as immune adjuvants. *Vaccine* 17: 19-25 (1999)
	BF	Kochel et al. Inoculation of plasmids expressing the dengue-2 envelope gene elicit neutralizing antibodies in mice. *Vaccine* 15(5): 547-552 (1997)
	BG	Wang et al., Immune Response to Neonatal Genetic Immunization. *Virology* 228: 278-284 (1997)
	BH	Dmitriev et al., Immunization with recombinant vaccinia viruses expressing structural and part of the nonstructural region of tick-borne encephalitis virus cDNA protect mice against lethal encephalitis. *J. Biotechnol.* 44: 97-103 (1996)
	BI	Hennessy et al., Effectiveness of live-attenuated Japanese encephalitis vaccine (SA14-14-2): a case-control study. *Lancet* 347: 1583-1586 (1996)
	BJ	Phillpotts et al., Immunization with DNA polynucleotides protects mice against lethal challenge with St. Louis encephalitis virus. *Arch. Virol.* 141: 743-749 (1996)
	BK	Sato et al., Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization. *Science* 273: 352-354 (1996)
	BL	Allison et al., Synthesis and Secretion of Recombinant Tick-Borne Encephalitis Virus Protein E in Soluble and Particulate Form. *J. Virol.* 69(9): 5816-5820 (Sept 1995)
	BM	Chen et al., Construction of Intertypic Chimeric Dengue Viruses Exhibiting Type 3 Antigenicity and Neurovirulence for Mice. *J. Virol.* 69(8): 5186-5190 (Aug 1995)

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	BN	dos Santos et al., Complete nucleotide sequence of yellow fever virus vaccine strains 17DD and 17D-213. *Virus Research* 35: 35-41 (1995)
	BO	Venugopal et al., Immunity to St. Louis encephalitis virus by sequential immunization with recombinant vaccinia and baculovirus derived PrM/E proteins. *Vaccine* 13(11): 1000-1005 (1995)
	BP	Mandl et al., Complete Genomic Sequence of Powassan Virus: Evaluation of Genetic Elements in Tick-Borne Versus Mosquito-Borne Flaviviruses. *Virology* 194: 173-184 (1993)
	BQ	Konishi et al., Mice Immunized with a Subviral Particle Containing the Japanese Encephalitis Virus prM/M and E Proteins Are Protected from Lethal JEV Infection. *Virology* 188: 714-720 (1992)
	BR	Wolff et al., Long-term persistence of plasmid DNA and foreign gene expression in mouse muscle. *Hum. Mol. Genet.* 1(6): 363-369 (Sept. 1992)
	BS	Konishi et al., Comparison of Protective Immunity Elicited by Recombinant Vaccinia Viruses That Synthesize E or NS1 of Japanese Encephalitis Virus. *Virology* 185: 401-410 (1991)
	BT	Mason et al., Japanese Encephalitis Virus-Vaccinia Recombinants Produce Particulate Forms of the Structural Membrane Proteins and Induce High Levels of Protection against Lethal JEV Infection. *Virology* 180: 294-305 (1991)
	BU	Falgout et al., Immunization of Mice with Recombinant Vaccinia Virus Expressing Authentic Dengue Virus Nonstructural Protein NS1 Protects Against Lethal Dengue Virus Encephalitis. *J. Virol.* 64(9): 4356-4363 (1990)
	BV	Nitayaphan et al., Nucleotide Sequence of the Virulent SA-14 Strain of Japanese Encephalitis Virus and Its Attenuated Vaccine Derivative, SA-14-14-2. *Virology* 177: 541-552 (1990)
	BW	Osatomi and Sumiyoshi, Complete Nucleotide Sequence of Dengue Type 3 Virus Genome RNA. *Virology* 176:643-647 (1990)
	BX	Bray et al., Mice Immunized with Recombinant Vaccinia Virus Expressing Dengue 4 Virus Structural Proteins with or without Nonstructural Protein NS1 Are Protected Against Fatal Dengue Virus Encephalitis. *J. Virol.* 63(6): 2853-2856 (1989)
	BY	Falgout et al., Proper Processing of Dengue Virus Nonstructural Glycoprotein NS1 Requires the N-terminal Hydrophobic Signal Sequence and the Downstream Nonstructural Protein NS2a. *J. Virol.* 63(5): 1852-1860 (1989)
	BZ	Roehrig et al., Synthetic Peptides Derived from the Deduced Amino Acid Sequence of the E-Glycoprotein of Murray Valley Encephalitis Virus Elicit Antiviral Antibody. *Virology* 171: 49-60 (1989)
	CA	Zhang et al., Passive Protection of Mice, Goats, and Monkeys Against Japanese Encephalitis With Monoclonal Antibodies. *J. Med. Virol.* 29: 133-138 (1989)
	CB	Hahn et al. Nucleotide Sequence of Dengue 2 RNA and Comparison of the Encoded Proteins with Those of Other Flaviviruses. *Virology* 162: 167-180 (1988)
	CC	Hashimoto et al. Molecular Cloning and Complete Nucleotide Sequence of the Genome of Japanese Encephalitis Virus Beijing-1 Strain. *Virus Genes* 1(3): 305-317 (1988)
	CD	Osatomi et al., Nucleotide Sequence of Dengue Type 3 Virus Genomic RNA Encoding Viral Structural Proteins. *Virus Genes* 2(1): 99-108 (1988)
	CE	Zhang et al., Immunization of Mice with Dengue Structural Proteins and Nonstructural Protein NS1 Expressed by Baculovirus Recombinant Induces Resistance to Dengue Virus Encephalitis. *J. Virol.* 62(8): 3027-3031(1988)
	CF	Mackow et al., The Nucleotide Sequence of Dengue Type 4 Virus: Analysis of Genes Coding for Nonstructural Proteins. *Virology* 159: 217-228 (1987)
	CG	Sumiyoshi et al. Complete Nucleotide Sequence of the Japanese Encephalitis Virus Genome RNA. *Virology* 161: 497-510 (1987)
	CH	Trent et al., Partial Nucleotide Sequence of St. Louis Encephalitis Virus RNA: Structural Proteins, NS1, ns2a, and ns2b. *Virology* 156: 293-304 (1987)

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	CI	Zhao et al., Expression of Dengue Virus Structural Proteins and Nonstructural Protein NS1 by a Recombinant Vaccinia Virus. *J. Virol.* 61(12): 4019-4022 (1987)
	CJ	Deubel et al., Nucleotide Sequence and Deduced Amino Acid Sequence of the Structural Proteins of Dengue Type 2 Virus, Jamaica Genotype. *Virology* 155: 365-377 (1986)
	CK	Kimura-Kuroda et al., Antigenic Comparison of Envelope Protein E between Japanese Encephalitis Virus and Some Other Flaviviruses Using Monoclonal Antibodies. *J. Gen. Virol.* 67: 2663-2672 (1986)
	CL	Zhao et al., Cloning Full-Length Dengue Type 4 Viral DNA Sequences: Analysis of Genes Coding for Structural Proteins. *Virology* 155: 77-88 (1986)
	CM	Rice et al., Nucleotide Sequence of Yellow Fever Virus: Implications for Flavivirus Gene Expression and Evolution. *Science* 229: 726-733 (1985)
	CN	Seeger et al., The cloned genome of ground squirrel hepatitis virus is infectious in the animal. *Proc. Natl. Acad. Sci. USA* 81(18): 5849-5852 (Sep 1984)
	CO	Kimura-Kuroda et al., Topographical Analysis of Antigenic Determinants on Envelope Glycoprotein V3 (E) of Japanese Encephalitis Virus, Using Monoclonal Antibodies. *J. Virol.* 45(1): 124-132 (1983)
	CP	Roehrig et al., Identification of Epitopes on the E Glycoprotein of Saint Louis Encephalitis Virus Using Monoclonal Antibodies. *Virology* 128: 118-126 (1983)
	CQ	Hunt and Calisher, Relationships of Bunyamwera Group Viruses by Neutralization. *Amer. J. Trop. Med. Hyg.* 28(4): 740-749 (1979)

EXAMINER:	DATE CONSIDERED:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.